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December 11, 1998

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Ms. Magalie Roman Salas Secretary **Federal Communications Commission** Room 222 1919 M Street, N.W. Washington, DC 20554

Re: RM-9157 - Ex Parte Notice

Dear Ms. Salas:

This is to note that on December 10, 1998, I met with Mr. Ari Fitzgerald, Legal Advisor to Chairman Kennard, to discuss the Petition for Rule Making filed by Medtronic, Inc., which asks the Commission to issue a notice of proposed rule making calling for the creation of the Medical Implant Communications Service. Copies of materials provided during the meeting are enclosed.

Sincerely,

David E. Hilliard

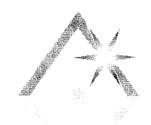
Counsel for Medtronic, Inc.

Enclosures:

Written Ex Parte Materials

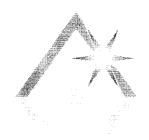
cc:

Ari Fitzgerald, Esq.



The Medical Implant Communications Service (MICS)

- ◆ On July 28, 1997, Medtronic filed its petition for rule making (RM-9157) asking the Commission to create the Medical Implant Communications Service as a new ultra low power (25 microwatt) personal radio service under Part 95 of the Rules without individual station licenses.
- ♦ MICS would provide for high capacity (100 kbs) data links in the 402 405 MHz band between implanted medical devices such as cardiac pacemakers and programmer/controller units for the rapid exchange of data for medical implant device adjustment and diagnosis of patient conditions.
- ♦ MICS will:
 - bring about beneficial changes in the surgical implantation of medical devices by removing communications equipment from the sterile field by operating with a range of 2 meters vs. the 8 centimeter range of current systems;
 - achieve a 40 fold increase in the speed of data communications involving medical implant devices to provide greater patient comfort and give physicians needed additional data;
 - improve both home health care and in-hospital monitoring;
 - open new telemedicine opportunities; and
 - increase the efficient use of both patient and physician resources by reducing the time needed for set-up and data exchange.



The Medical Implant Communications Service (MICS)

Additional background:

- ◆ RM-9157 appeared on public notice and drew only support.
- ♦ The 402-405 MHz band can support MICS operations worldwide as a secondary mobile application in spectrum allocated primarily for use by meteorological aids such as transmitters used with weather balloons.
- ♦ Working with members of U.S. Working Party 7-C, which includes federal users of the 402 406 MHz band, Medtronic has shown the compatibility of MICS with current users of the band. MICS, as proposed in the U.S. by Medtronic, would involve only the 402 405 MHz portion of that band. In February 1998 the ITU-R announced in Geneva the adoption of Recommendation ITU-R SA.1346, which concludes that use of the 401-406 MHz band for MICS would be compatible with existing meteorological users of the band.
- ♦ In May of 1998 CEPT/ERC/FM Working Group approved designation of the 402-405 MHz band for Ultra Low Power Medical Implants applications and designated ETSI standard EN 300 220 as the applicable product standard in Europe.
- ♦ MICS is not a replacement for current low power medical telemetry systems. MICS will serve different applications. A need will still exist for 5 to 20 milliwatt systems of the sort now authorized under Part 90 of the Rules and 100 milliwatt systems authorized under the Part 95 Low Power Radio Service.
- ♦ With revenues of more than 2.5 billion dollars, Medtronic, Inc., based in Minneapolis, Minnesota, is the world's leading manufacturer of cardiac pacemakers, defibrillators and neurological devices. More than one million patients benefited last year from Medtronic technology.

For information about MICS, please contact:
David Hilliard of Wiley, Rein & Fielding
1776 K Street, N.W., Washington, DC 20006
202-429-7058, 202-429-7049 (fax)

Milestones in the Development of the Medical Implant Communications Service

- <u>July 1995</u> Medtronic personnel first met with the FCC (OET staff). After consultation, the OET staff suggest that 401 406 MHz be investigated as a possible band for MICS.
- February 1996 Medtronic submitted to U.S. ITU-R Working Party 7C its proposal for compatible sharing in the 401 406 MHz band between MICS and Meteorological Aids.
- March 1996 Medtronic personnel met with the National Telecommunication Information Agency (NTIA) staff regarding secondary sharing of the 401-406 MHz band in the United States.
- <u>December 1998</u> Medtronic representatives met with FCC Office of Engineering and Technology officials to discuss regulatory options for ultra low power medical telemetry for medical implant devices. Medtronic representatives then met with officials from the FCC's Wireless Telecommunications Bureau.
- <u>July 1997</u> Medtronic filed its petition for rule making proposing that the FCC create under Part 95 the Medical Implant Communications Service (MICS).
- January 1998 Medtronic briefed advisors to FCC Commissioners about MICS.
- February 1998 ITU announced in Geneva that Recommendation ITU-R SA.1346 had been approved concluding that use of the 401-406 MHz band for MICS would be compatible with existing meteorological users of the band.
- May 1998 CEPT/ERC/FM Working Group approved designation of the 402-405 MHz band for Ultra Low Power Medical Implants (MICS) applications and designated ETSI standard EN 300 220 as the applicable product standard.
- July 1998 Medtronic personnel briefed Wireless Telecommunication Bureau (WTB) staff and FDA staff in a meeting designed to provide technical background on the MICS system operating parameters.
- October 1998 ITU formally published Recommendation ITU-R SA.1346 finding that use of the 401-406 MHz band by MICS equipment would be compatible with existing meteorological users of the band.

- Section 7 [47 USC Section 157]. New Technologies and Services
- (a) It shall be the policy of the United States to encourage the provision of new technologies and services to the public. Any person or party (other than the Commission) who opposes a new technology or service proposed to be permitted under this Act shall have the burden to demonstrate that such proposal is inconsistent with the public interest.
- (b) The Commission shall determine whether any new technology or service proposed in a petition or application is in the public interest within one year after such petition or application is filed. If the Commission initiates its own proceeding for a new technology or service, such proceeding shall be completed within 12 months after it is initiated.